Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of the claims in the application.

Listing of Claims

1. (Currently amended) A pharmaceutical composition comprising

(i) a biologically active agent;

(ii) ~~an~~ a first adjuvant chemical which increases the effect of the biologically active agent, said chemical selected from one or more of:

A) ~~a polyamino acid~~ polyornithine,

B) a water soluble vitamin or water soluble vitamin derivative,

C) a positively charged cationic ~~pluronics~~ block copolymer or a positively charged cationic surfactant,

D) a clathrate,

E) a complexing agent,

F) cetrimides,

G) an S-layer protein, or

H) Methyl-glucamine; and

(iii) a pharmaceutically acceptable carrier or diluent; subject to the following provisos

a) when the chemical (ii) above is selected from D) or E), the biologically active agent is an agent ~~which is capable of generating~~ that generates a protective immune response in an animal to which it is administered;

b) when the chemical (ii) above is selected from A) and the biologically active agent is an agent ~~which is capable of generating~~ that generates a protective immune response in an animal to which it is administered, the composition is for administration to a mucosal surface,

c) when the chemical (ii) above is selected from C) and the biologically active agent is an agent ~~which is capable of generating~~ that generates a protective immune response in an animal to which it is administered, the composition does not contain a polyacrylic acid, and

d) when the chemical (ii) above is selected from G) and the biologically active agent is an agent ~~which is capable of generating~~ that generates a protective immune response in an animal to which it is administered, the carrier or diluent of (iii) is a microsphere or liposome.

2. (Currently amended) ~~A~~ The composition ~~according to~~ of claim 1 wherein the biologically active agent is an agent that ~~is capable of generating~~ generates a protective immune response in an animal to which it is administered.

3. (Currently amended) ~~A~~ The composition ~~according to~~ of claim 1 wherein the ~~said~~ adjuvant chemical ~~can act~~ acts as an immunostimulant.

4. (Currently amended) ~~A~~ The composition ~~according to~~ of claim 1 wherein the said adjuvant chemical is selected from one or more of;

A) the poly-ornithine has a~~, for example of~~ molecular weight from 5 to 150kDa;

B) the water soluble vitamin ~~vitamins~~ or water soluble vitamin derivative ~~derivatives~~ is ~~such as~~ vitamin E TPGS (d-alpha tocophenyl polyethylene glycol 1000 succinate),

C) the cationic ~~pluronics which are~~ block copolymer ~~copolymers~~ or the cationic surfactant is ~~surfactants which are~~ positively charged by means of~~, in particular with~~ NH_2^+ groups

D) the complexing agent forms ~~agents which form~~ complexes with fatty acids ~~such as deoxycholic acid~~, or

E) the clathrate is a cyclodextrin or a derivative thereof ~~cyclodextrins and their derivatives such as dimethyl β cyclodextrin~~.

5. (Currently amended) ~~A~~ The composition ~~according to~~ of claim 1 wherein the carrier comprises a particle.

6. (Currently amended) ~~A~~ The composition ~~according to~~ of claim 5 wherein the particle is a microsphere or liposome.

7. (Currently amended) ~~A~~ The composition ~~according to~~ of claim 6 which comprises a microsphere.

8. (Currently amended) ~~A~~ The composition ~~according to~~ of claim 7 wherein the microsphere is prepared using a high molecular weight polymer.

9. (Currently amended) ~~A~~ The composition ~~according to~~ of claim 8 wherein the polymer has a molecular weight of 100kDa or more.

10. (Currently amended) ~~A~~ The composition ~~according to~~ of claim 7 wherein the microsphere comprises poly-(L-lactide).

11. (Currently amended) ~~A~~ The composition ~~according to~~ of claim 1 wherein the ratio of the chemical (ii) to the carrier (iii) is from 99:1 to 9:1 w/w.

12. (Currently amended) ~~A~~ The composition ~~according to~~ of claim 1 which is ~~adapted for administration to a mucosal surface or is suitable for parenteral administration~~ administered to a mucosal surface of the animal or administered parenterally to the animal.

13. (Currently amended) ~~A~~ The composition ~~according to~~ of claim 2 which further comprises a ~~further~~ second adjuvant.

14. (Withdrawn) A method of producing a prophylactic or therapeutic vaccine, which method comprises encapsulating a polypeptide which is capable of producing a protective immune response in a first polymeric material which has a high molecular weight, in the presence of a second polymeric material which increases the biological effect of the composition.

15. (Withdrawn) A method of protecting a mammal against infection, which method comprises administration of a composition according to claim 1 to a mammal.

16. (Withdrawn) A method according to claim 15 wherein the composition is applied to a mucosal surface.

17. (Withdrawn) A method according to claim 16 wherein the mucosal surface comprises an intranasal surface.

18. (Withdrawn) A microsphere comprising a polymeric carrier and an S-layer protein.

19. (Withdrawn) A microsphere according to claim 18 wherein said S-layer protein is coated on the surface of the microsphere.

20. (Withdrawn) A microsphere according to claim 18 which further comprises an agent that is capable of generating a protective immune response in an animal to which it is administered.

21. (Withdrawn) A microsphere according to claim 20 wherein one or more of said agents are linked to the S-layer protein.

22. (Withdrawn) A pharmaceutical composition comprising a microsphere according to claim 19.

23. (Withdrawn) A pharmaceutical composition according to claim 22 wherein said composition is a vaccine, intended to produce a protective immune response against a bacterium, and said S-layer protein is derived from said bacterium.

24. (Withdrawn) The use of a chemical selected from

A) a polyamino acid,

B) a water soluble vitamin or vitamin derivative,

C) positively charged cationic pluronics,

D) a clathrate,

E) a complexing agent,

F) cetrimides,

G) an S-layer protein, or

H) Methyl-glucamine

as an immunostimulant, provided that in the case of A), the immunostimulant is applied to a mucosal surface, in the case of C, the compound is used in the absence of a polyacrylic acid.

25. (Withdrawn) The use of an adjuvant chemical selected from

A) a polyamino acid,

B) a water soluble vitamin or vitamin derivative,

C) positively charged cationic pluronics,

D) a clathrate,

E) a complexing agent,

F) cetrimides,

G) an S-layer protein, or

H) Methyl-glucamine

as an immunostimulant in the production of a vaccine for use in prophylactic or therapeutic treatment, provided that in the case of A), the immunostimulant is used in a vaccine which is

applied to a mucosal surface, in the case of C), the compound is used in the absence of a polyacrylic acid.

26. (New) The composition of claim 4 wherein

A) the complexing agent forms complexes with deoxycholic acid; or

B) the clathrate is dimethyl-β-cyclodextrin.